IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Greg Swords	)	
	)	Art Unit: 3738
Serial No. 10/517,843	)	
	)	
Filed: July 12, 2005	)	Examiner: Suba Ganesan
	)	
For: Craniofacial Implant	)	Attorney Docket No.: 37370/339252

DECLARATION OF GREG SWORDS
REGARDING COMMERCIAL SUCCESS OF TITAN IMPLANT

1. My name is Greg Swords. I am over the age of 21, and I am competent to make this declaration based upon my personal knowledge.

2. I am the named inventor of the above-referenced patent application. I am also presently Vice President of Market Applications and Development at Porex Surgical, Inc., the assignee of the above-referenced patent application.

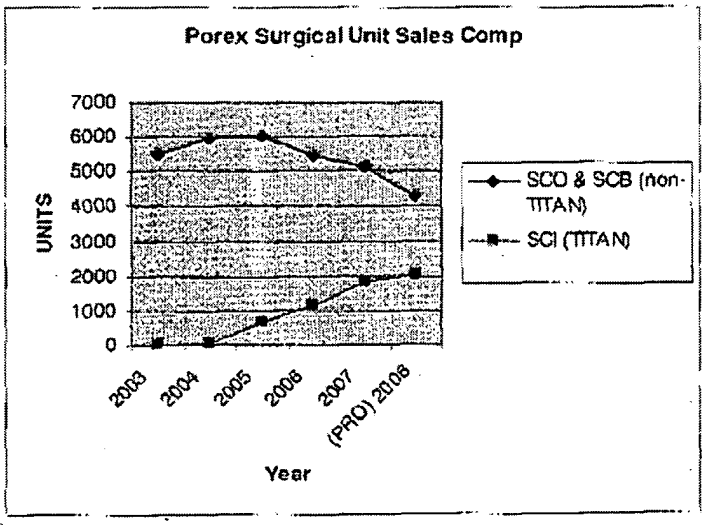
3. Porex Surgical, Inc. is currently manufacturing and selling a product called the TITAN™ Implant, which is covered by the claims of the above-referenced patent application and described at the following website:

http://www.porexsurgical.com/english/surgical/sprodtitan_sheets.asp

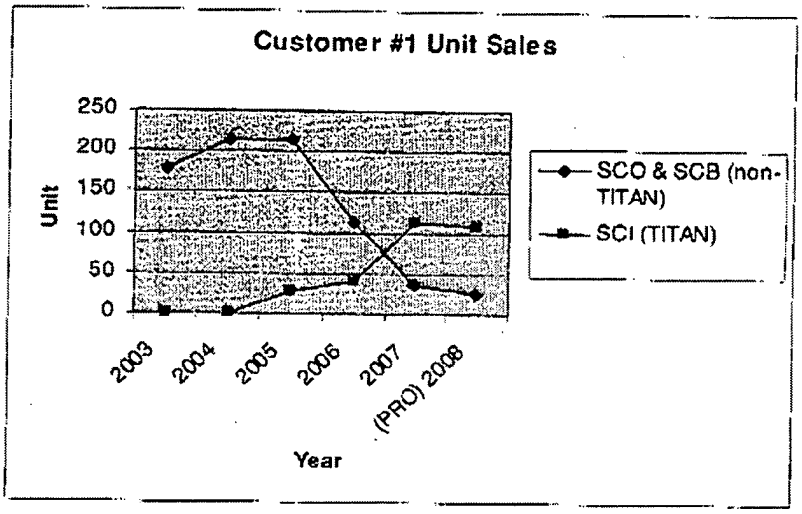
4. As background, porous polyethylene implants for orbital reconstruction *without* a surgical grade metal mesh contained therein have been marketed and sold by Porex and other companies. Metal mesh alone (not contained within porous polyethylene) has also been sold by other companies as an option for bone reconstruction.

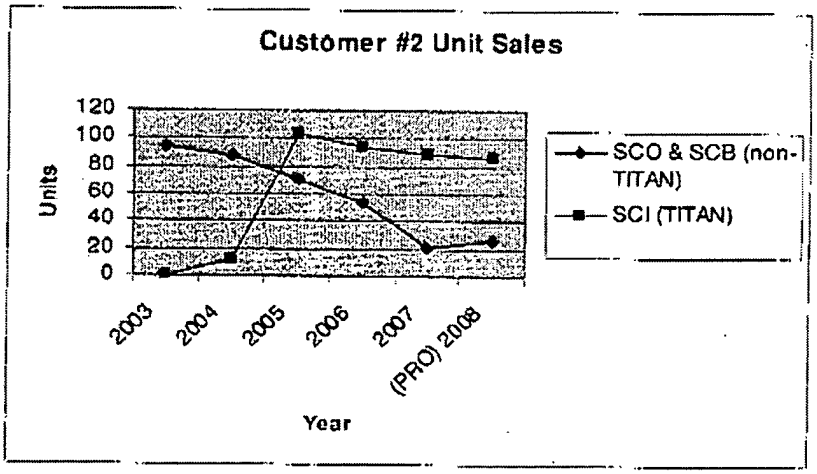
5. When Porex introduced the TITAN™ Implant, which includes a polyethylene matrix having a surgical grade metal mesh embedded therein, sales of the TITAN™ implants steadily increased when compared to the sales of implants without an embedded metal mesh. In fact, as shown below, sales of the implants without a metal mesh declined.

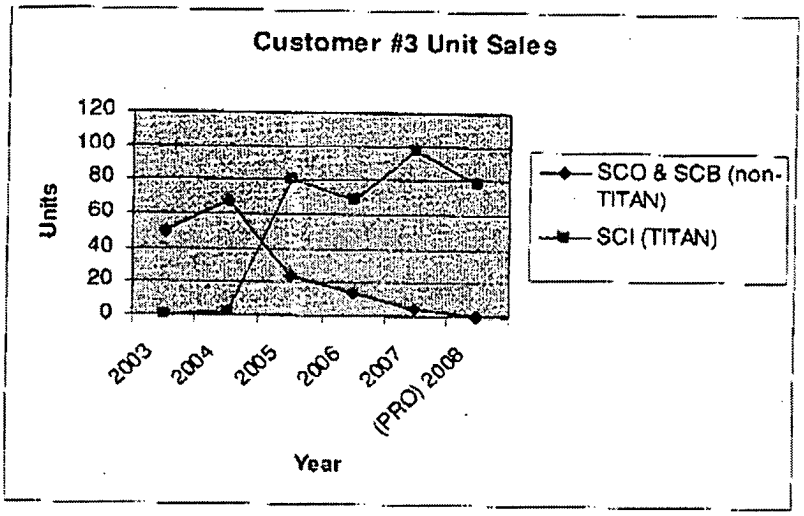
6. The below charts show unit sales of TITAN™ implants vs. Porex's implants without a metal mesh. The first chart reflects total unit sales for Porex as a whole, and illustrates that sales of the TITAN™ implants increased, while sales of non-TITAN™ implants decreased.

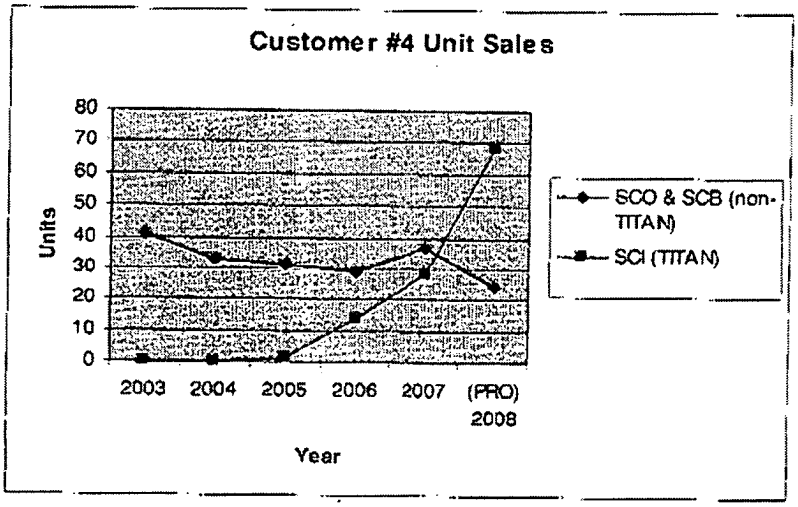


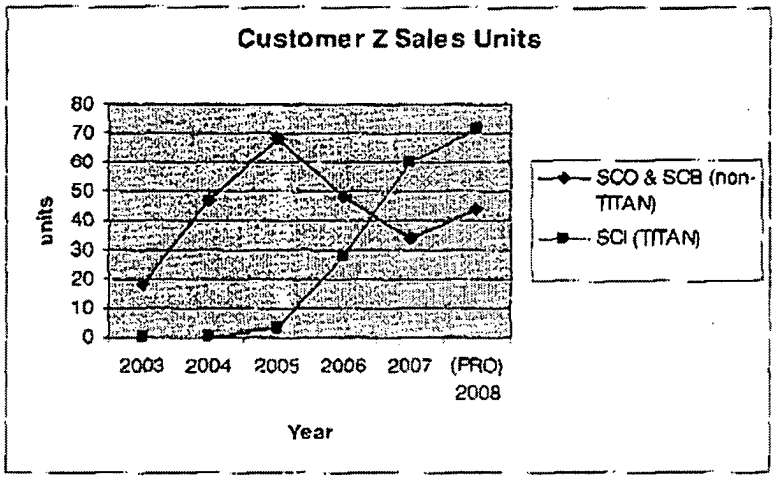
The following charts reflect unit sales to some of Porex's top TITAN™ customers.






Customer #3 Unit Sales
120
100
80
60
40
20
0
Units
2003
2004
2005
2006
2007
(PRO) 2008
Year
SCO & SCB (non-TITAN)
SCI (TITAN)


Customer #4 Unit Sales
80
70
60
50
40
30
20
10
0
Units
2003
2004
2005
2006
2007
(PRO) 2008
Year
SCO & SCB (non-TITAN)
SCI (TITAN)



7. These charts do not reflect *revenues* generated, but *units* sold. This is relevant because the TITAN™ implants are more expensive than Porex's implants without a metal mesh. Nonetheless, more TITAN™ units are steadily being purchased and fewer implants without metal mesh are being purchased.

8. Since the introduction of the TITAN™ Implant, Porex has captured a number of completely new customers. Additionally, many customers who previously purchased the implants without the metal mesh have switched to the TITAN™ implants, particularly for their more complex cases.

9. Upon its introduction, Porex did not advertise its TITAN™ implants any differently from the way Porex advertised its earlier implants. The same methods of promotion were used and similar expenditures were made to advertise both types of implant. The press and recognition that the TITAN™ implants have received by the medical community is solely due to its features, which are described and claimed in the above-referenced patent application.

10. The articles attached at Tab A to this declaration describe the success that surgeons are having with the TITAN™ implant. These articles describe the beneficial features of the implant itself, and not other economic or commercial factors unrelated to the technical quality of the claimed subject matter.

11. The surgeon's declarations attached at Tab B also attest to the technical qualities of the implants, and not other economic or commercial factors unrelated to the technical quality of the claimed subject matter. These declarations evidence that surgeons are demanding the TITAN™ implant because of its specific features.

12. As the person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

Dated: 8-22-08

Name: Greg Swords
Citizenship: USA
Post Office Address: 15 DART Rd
NEWNAN GA 30265

TAB A

47. Porous Polyethylene Implants With Embedded Titanium Mesh: Use in Orbital Fracture Repair and Computed Tomography Visualization

Charles V. Duss, M.D., Paul D. Langer, M.D., New Jersey Medical School, Newark, NJ

Introductory Sentence: Over the past fifteen years, porous polyethylene implants have been successfully used in the surgical repair of orbital fractures with excellent cosmetic and functional results; however, radiographic visualization of these implants postoperatively is difficult. A newer version of the implant (Medpor TITAN™) combines the biologically integrative property of the traditional porous polyethylene implant with a radiographically visible titanium core. We report our early experience with this implant in the repair of orbital fractures.

Methods: The charts of all patients since November 2004 presenting with new orbital wall fractures, from the practice of one surgeon (PDL), were reviewed. Patients undergoing surgical correction with placement of a polethylene implant with embedded titanium were included in the study. Clinical outcome, patient tolerance, and visibility of the implant on postoperative computed tomography (CT) scans were assessed.

Results: Of thirty-eight new patients with orbital wall fractures, eighteen required surgical repair to address significant enophthalmos and/or persistent diplopia. Each patient underwent the transconjunctival placement of a porous polyethylene implant containing embedded titanium mesh following the surgical repositioning of herniated orbital tissue. After an average follow up of six months, all eighteen patients achieved satisfactory clinical outcomes based on reduction of enophthalmos and/or diplopia, with no significant adverse reactions to the implants. No cases of postoperative infection or implant extrusion were observed during the study period. Fifteen of the eighteen patients underwent postoperative orbital CT scans, and in each case the implant was well visualized.

Conclusions: Porous polyethylene implants containing embedded titatium mesh combine the advantage of traditional porous polyethylene implants (the capacity for fibrovascular ingrowth) with the additional feature of radiographic density. In this early retrospective study, patients tolerated the implant well, and most importantly, precise radiologic localization of the implant was achieved postoperatively due to the visibility of the titanium mesh on CT scan. The Medpor TITAN™ implant may be an excellent alternative to a traditional porous polyethylene implant when postoperative imaging of the implant is critical.

Bibliography: 1. Rubin P.A., et al. Orbital reconstruction using porous polyethylene sheets. *Ophthalmology.* 101(10):1697-708, 1994. 2. Choi JC, Sims CD, Casanova R, Shore JW, Yaremchuk MJ. Porous polyethylene implant for orbital wall reconstruction. J Craniomaxillofac Trauma. 1995 Fall;1(3):42-9.

Author Disclosure Block: **C.V. Duss**, None; **P.D. Langer**, None.

4:25 pm

Medpor TITAN®: A New Alloplastic Orbital Implant

Shannath L. Merbs, M.D.., Ph.D., Daniel C. Garibaldi, M.D., Michael P. Grant, M.D., Ph.D., Nicholas T. Iliff, M.D., Wilmer Eye Institute, Baltimore, MD

Abstract Body:

Introductory Sentence: We have examined the effectiveness of a new orbital implant, MEDPOR TITAN, which combines the benefits of both porous polyethylene and titanium mesh, in the reconstruction of orbital defects.

Methods: Thirty consecutive patients receiving at least one MEDPOR TITAN plate during orbital reconstruction by the authors were studied as a retrospective, non-comparative case series. Patient charts and pre-operative and post-operative scans were reviewed for any complications associated with the implant. Surgeons were questioned as to the advantages and disadvantages of the new implant, which became commercially available in October 2004.

Results: 20 men and 10 women underwent placement of at least one MEDPOR TITAN implant. Patient ages ranged from 3 to 85 (mean 35). 28 patients had acute fracture repair (19 floor fractures, 2 medial wall fractures, and 7 floor and medial wall fractures), 1 patient had late enophthalmos repair, and 1 patient had orbital reconstruction after tumor removal. Both 1.0 mm-thick MTB (MEDPOR TITAN BARRIER) and 0.6 mm-thick BTB (MEDPOR TITAN Double BARRIER) implants were used and were typically fixated with 1 or 2 microscrews. No short-term complications were noted, and patients continue to be followed for evidence of long term complications. Surgeons reported that the implants were easy to cut and shape, had sufficient tensile strength to maintain their contour, and were well-visualized on post-operative CT scans. Conclusions: Many alloplastic materials have been used in orbital reconstruction, each with its own profile of advantages and disadvantages. The MEDPOR TITAN implant, with several advantages over other currently available implants, represents a new alloplastic alternative.

Bibliography: Romano JJ, Iliff NT, Manson PN. Use of Medpor porous polyethylene implants in 140 patients with facial fractures. J Craniofac Surg. 1993 Jul;4(3):142-7. Rubin PA, Bilyk JR, Shore JW. Orbital reconstruction using porous polyethylene sheets. Ophthalmology. 1994 Oct;101(10):1697-708. Ng SG, Madill SA, Inkster CF, Maloof AJ, Leatherbarrow B. Medpor porous polyethylene implants in orbital blowout fracture repair. Eye. 2001 Oct;15(Pt 5):578-82.

Author Disclosure: S.L. Merbs, Porex I; **D.C. Garibaldi**, Porex I; **M.P. Grant**, Porex I; **N.T. Iliff**, Porex I.

46. Repair of Internal Orbital Wall Fractures Using Porous Polyethylene/ Titanium (TITAN) Orbital Implants

David E.E. Holck, M.D., Wilford Hall Medical Center, San Antonio, TX

Introductory Sentence: Multiple alloplastic materials exist in the repair of internal orbital wall fractures. Each is associated with complications unique to that material. Materials combining the benefits of stability from fibrovascular ingrowth with the rigidity of a metal would offer benefits that exceed each individual substance alone. We evaluated a modified design of the porous polyethylene/ titanium implant (TITAN, POREX Surgical, Newnan, GA) on large orbital floor and combined floor/ medial wall fractures.

Methods: Nineteen orbital fractures in 17 patients were treated using a TITAN orbital implant. Twelve fractures involved large orbital floor areas without adequate posterior support, and seven were combined orbital floor and medial wall fractures. For combined floor and medial wall fractures, a custom designed plate was used to conform to the floor and medial wall. Footplates were cut for rigid fixation over the orbital rim. Postoperative evalution included computed tomography, and clinical evaluation at (at least) postoperative day one, week one, months one, three and six.

Results: In all cases, adequate reduction of the orbital fracture was obtained. No cases of clinical motility restriction from incarceration of orbital soft tissue to the implant surface have been observed. One patient was noted to have 1.5mm of hyperglobus postoperatively. Three fractures were noted to have the orbital plate impinging on the rectus muscles at the posterior aspect of the implant, but these did not have clinical sequelae. No cases of bleeding, infection, migration, extrusion, exposure, or need for explantation were encountered.

Conclusions: For large orbital floor fractures without adequate posterior support or combined orbital floor and medial wall fractures, the TITAN orbital implant provides appropriate fracture reduction. Footplates cut from the material may be rigidly screwed to the orbital rim providing fixation. The material is available with a barrier surface that prevents adhesions from othe orbital soft tissue to the implant, while having a porous side that facilitaes fibrovascular adhesions for additional stability. The same benefits of rigidity and minimal implant memory must be taken into consideration when placing the implant to avoid the complication of orbital soft tissue incarceration.

Bibliography: 1. Sugar AW, Kuriakose M, Walshaw ND. Titanium mesh in orbital wall reconstruction. Int J Oral Maxillofac Surg. 1992; 21: 140-144. 2. Choi JC, Fleming JC, Aitken PA, Shore JW. Porous polyethylene channel implants: a modified porous polyethylene sheet implant designed for repairs of large and complex orbital fractures. OPRS. 1999;15(1):56-66.

Author Disclosure Block: **D.E.E. Holck**, None.

Internal Orbital Wall Fracture Repair Using Porous Polyethylene/ Titanium Mesh (MEDPOR® TITAN™) Implants

Authors: David EE Holck, MD, Thomas Dahl, MD
Wilford Hall Medical Center, San Antonio, Texas

Jill A Foster, MD
Ophthalmic Consultants of Ohio, Columbus, Ohio

John D Ng, MD
Casey Eye Institute, Oregon Health Sciences Center, Portland, Oregon

Introduction:

The complex nature of bony orbital fractures and their impact upon orbital soft tissue structure and visual function presents a particular challenge to the orbital surgeon. The tenants of surgical management of symptomatic orbital fractures involve open reduction of the fracture, release of the entrapped tissues, repositioning of the herniated orbital soft tissue within the orbit, and repair of the post-traumatic defect with an orbital implant as needed. The orbital implant restores the structural integrity of the orbital wall by bridging the defect and preventing orbital contents from herniating into the adjacent periorbital sinuses. The implant should prevent extra-ocular motility limitations by minimizing scar tissue adhesion with orbital contents. These implants can also serve to augment the orbital volume by compressing the intraorbital contents to correct enophthalmos.[1] Current implants include autogenous grafts, human donor grafts, xenografts and alloplastic implants. The ideal alloplastic implant has been described as readily sizeable, sterilizable, strong, inert, non-allergenic, durable, non-carcinogenic, easily manipulated and shaped, and suitable for single stage reconstruction.[2] Implants should be accepted and well integrated into the surrounding tissues with minimal inflammatory response, foreign body reaction, or risk of infection. The implant should provide mechanical support strong enough to hold up the orbital contents, and have the ability to be easily anchored to the surrounding bone to prevent migration and extrusion. Finally, it should be readily available in larger quantities if necessary, at a reasonable cost.

Porous polyethylene orbital sheets offer strength and stability, with porous channels that allow fibrovascular ingrowth. The implants exhibit memory upon bending, which must be considered during placement in the orbit.[3] Fenestrated and mesh titanium implants also allow excellent strength and stability characteristics without memory after the material has been conformed to fit the orbital contours and defect. However, removal of the implant can prove to be a difficult task once tissue ingrowth has occurred.[4] Scarring to the exposed metallic mesh with dysmotility is an additional reported complication.[5]

Recently, a porous polyethylene sheet with titanium mesh has been available for use in non-weight bearing applications as seen with internal orbital fractures (TITAN™ implants, MEDPOR® Surgical, Newnan, GA, USA). We evaluated the utility of this material in large floor and combined floor/ medial wall fractures. (Figs. 1 - 2)

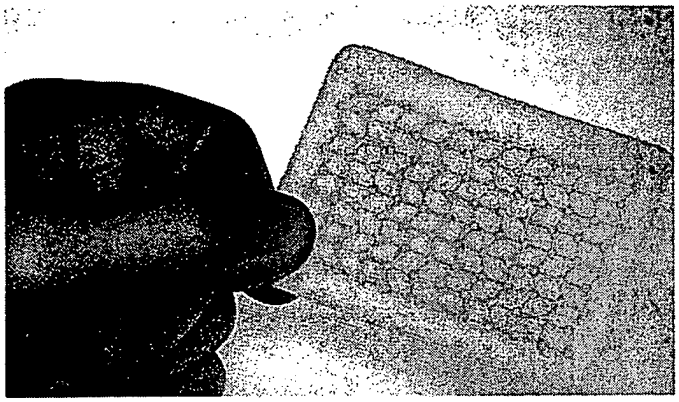


Fig. 1. MEDPOR TITAN orbital implant with porous polyethylene coated titanium

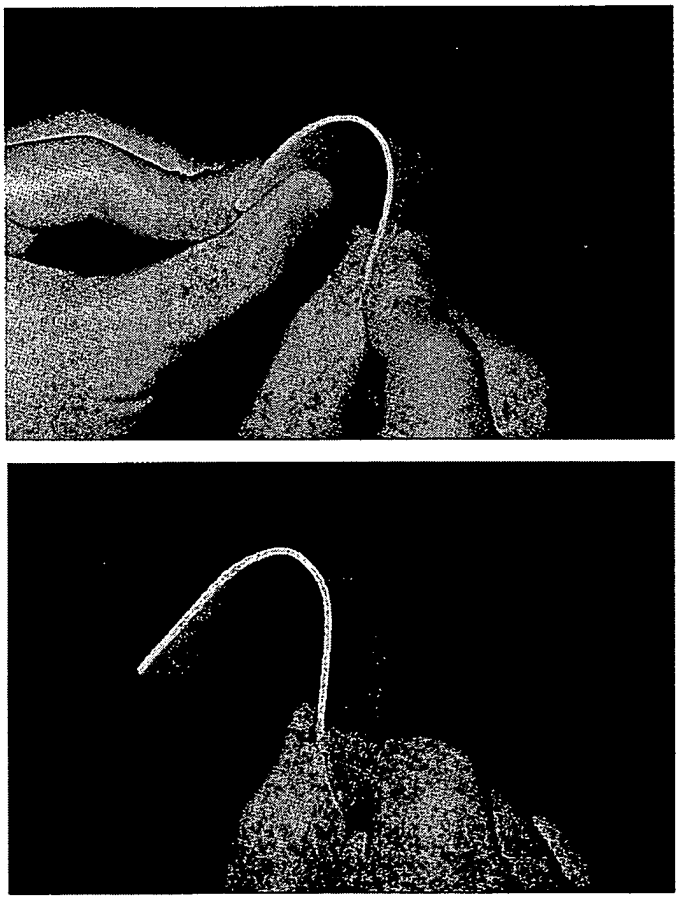


Fig. 2. MEDPOR TITAN orbital implant bent to demonstrate lack of implant "memory"

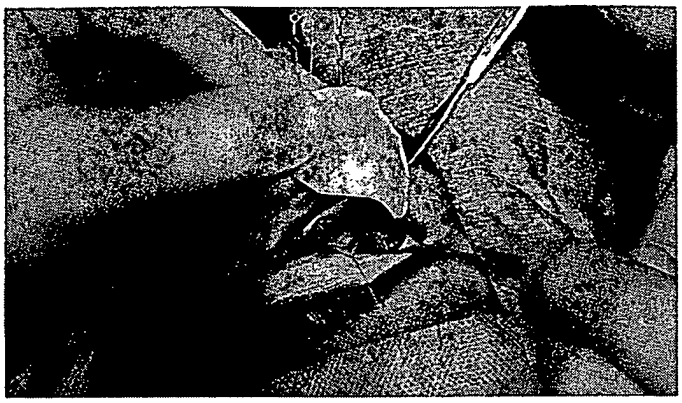
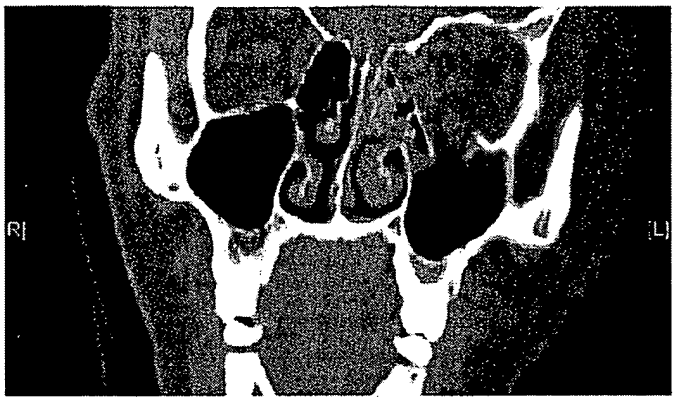


Fig. 3. Intraoperative TITAN plate cut and pre-bent to cover an orbital floor and medial wall defect

Materials/Methods:

Fourteen patients with extensive orbital floor (8 patients) fractures (with minimal posterior support) and combined orbital floor and medial wall (6 patients) fractures underwent surgical repair between 9/04 and 4/05. Each patient had the orbital fracture reduced using the TITAN orbital implant (MEDPOR, Newnan GA). The patients were followed postoperatively for a minimum of six months. In addition to clinical evaluation of ocular position (globe dystopia, enophthalmos), ocular function was evaluated at each visit.

In all cases, the implant was placed through a swinging eyelid transconjunctival approach with or without a transcaruncular incision. (Fig. 3) In each patient, a single-sided barrier facing the orbital soft tissue was used to avoid potential scar adhesions to the implant. The plates were fixated in position using screw fixation to the orbital rim. The patients were examined preoperatively at (at least) one day, one week, and one, three and six months postoperatively. In each case, a postoperative computed tomogram was obtained to verify implant position (as the titanium mesh was easily visible) (Figs. 4 - 7).



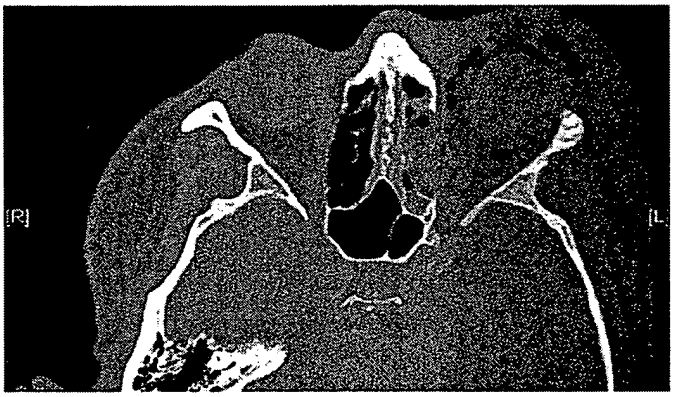
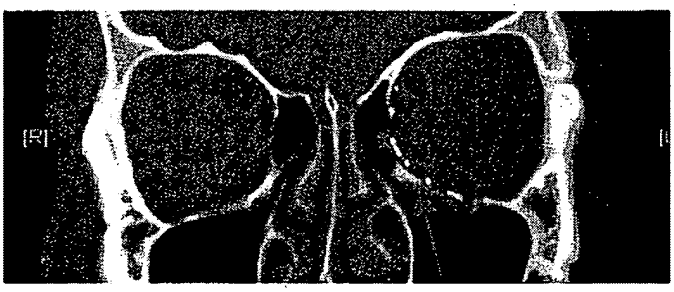


Fig. 4. Preoperative coronal and axial computed tomography views of patient (Case 7) with a combined medial orbital wall and floor fracture affecting the left orbit.



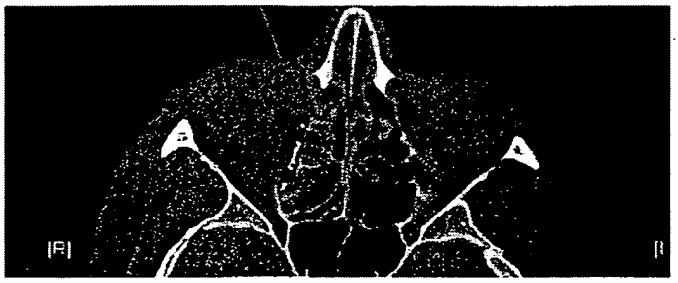


Fig. 5. Coronal and axial views of computed tomogram (Case 7) demonstrating TITAN placement in medial wall and orbital floor fracture repair (arrows).

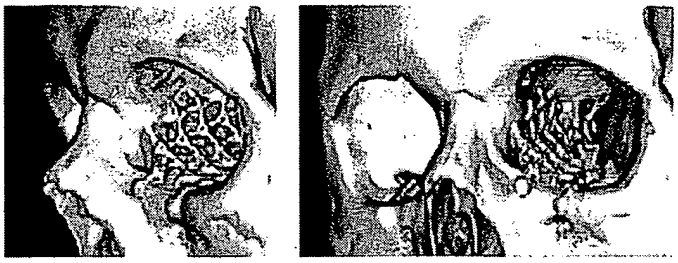


Fig. 6. 3-D computed tomogram demonstrating TITAN implant position (Case 7) after a combined medial wall and floor fracture repair.

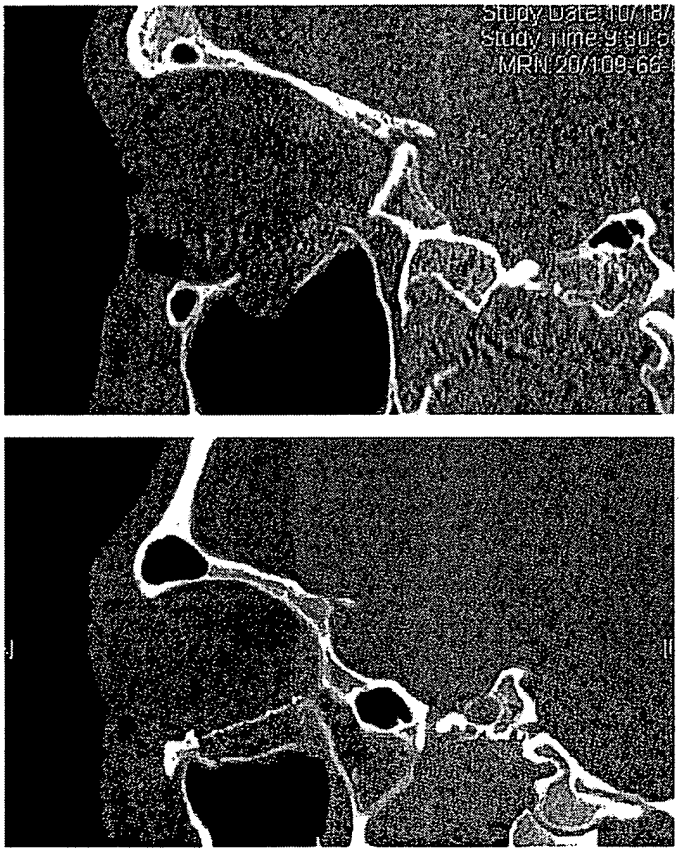


Fig. 7. Sagittal postoperative view (Case 2) of combined orbital floor and medial wall fracture demonstrating adequate posterior placement of TITAN implant (bottom image).

Results:

Intraoperatively, the porous polyethylene covering of the titanium mesh allowed smoother edges of the titanium mesh after cutting facilitating implant

placement. Additionally, the implant was bent to conform to the contours of the intact bony ledges surrounding the fracture site. The titanium mesh minimized the memory of the bent implant, facilitating placement.

Postoperatively, none of the implants required removal or repositioning. Postoperative computed tomography verified implant placement in all cases. In one patient (Case 7), verification of correct implant position was useful to avoid a return to the operating room in a patient with unimproved postoperative dysmotility. In this case, the lack of improvement was related to inferior rectus trauma (and hematoma), and has slowly improved over the six months postoperatively. In one patient (Case 4), 1.0mm of hyperglobus was noted postoperatively, which was not concerning to the patient, and she refused additional surgery. This patient received a 1.5mm thick implant.

Conclusions:

Porous polyethylene covered titanium mesh results in increased implant strength and decreased memory. These characteristics offer distinct advantages over traditional alloplastic implants in the management of internal orbital fractures. The increased strength of the implant from the titanium mesh allows a thinner implant (it is available in thicknesses ranging from 0.85-1.6mm) that avoids the abaxial displacement that may be seen with thicker implants such as the channeled porous polyethylene implant (thickness 2.3mm). The lack of memory associated with bending porous polyethylene sheets allows greater implant stability using the TITAN implants. Care must be taken to correctly conform to the orbital defect, as "overbending" the implant may result in soft tissue incarceration. Immobilization of the implant using screw or suture fixation also provides increased implant stability. The implant is available with an impermeable barrier surface on one (BTM) or both (BTB) sides, and also without a barrier surface (MTM). The orbital barrier surface may also inhibit adhesions from orbital soft tissue to the surface of the implant, while the posterior surface facing the sinus mucosa may vascularize offering additional implant stability. Additionally, the titanium mesh allows postoperative imaging to verify implant placement, which may be critical in those situations where adequate postoperative soft tissue release needs to be demonstrated.

Isolated single orbital wall fractures with adequate intact bony ledges for implant coverage may be easily and successfully repaired with most currently available implant materials available at reduced costs. However, the TITAN orbital implant sheets provide a distinct advantage in large single wall fractures, multiple internal wall fractures (orbital floor and medial wall) or those floor fractures with inadequate posterior support requiring an implant with greater strength.

Table 1. Cases of TITAN use. M-male; F-female; MVA-motor vehicle accident; IED-improvised explosive device; BTM-barrier/titanium/MEDPOR; BTB-barrier/titanium/barrier; MTM- MEDPOR/titanium/MEDPOR

Case	Age	Gender	Mechanism of injury	Diagnosis	Additional injuries	Implant	Date of Surgery	Compli-cations	Follow-up (mo's)
1	34	M	Sport injury	Large floor fracture	None	1.0mm BTM	10/04	None	12
2	27	M	MVA	Large floor fracture	Facial lacerations	1.0mm BTM	10/04	None	12
3	37	M	Assault	Posterior Floor Fracture	None	1.0mm BTM	11/04	None	11
4	36	F	Assault	Orbital floor/ medial wall fracture	None	1.6mm BTM	11/04	1.0mm hyperglobus	11
5	27	M	IED	Orbital floor/ medial wall fracture	Traumatic optic neuropathy	1.0mm BTM	12/04	None	10
6	42	M	MVA	Posterior floor Fracture	None	1.0mm BTM	1/05	None	9
7	25	M	Assault	Orbital floor/ medial fracture	Facial lacerations	1.0mm BTM	1/05	None	9
8	36	M	Sports injury	Orbital floor/ medial wall fracture	None	1.0mm BTM	1/05	None	9
9	75	F	Fall	Large floor fracture	None	1.0mm BTM	2/ 05	None	8
10	23	M	IED	Orbital floor/ medial wall fracture	Orbital foreign bodies	1.0mm BTM	2/05	None	7
11	24	M	MVA	Posterior floor fracture	Lid laceration	1.0mm BTM	3/05	None	7
12	26	M	MVA	Orbital floor/ medial wall fracture	Facial lacerations	1.0mm BTM	4/05	None	6
13	23	M	Assault	Large floor fracture	None	1.0mm BTM	4/05	None	6
14	38	M	MVA	Large floor fracture	Facial laceration	1.0mm BTM	4/05	None	6

References:

1. Costantino PD, Hiltzik DH, Friedman CD, et al. Alloplastic plating techniques in orbital fracture repair (Chapter 20). In Holck, Ng Eds.: Evaluation and Treatment of Orbital Fractures, a Multidisciplinary Approach. 2005, Philadelphia, Saunders-Elsevier.

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4. Sugar AW, Kuriakose M, Walshaw ND. Titanium mesh in orbital wall reconstruction. Int J Oral Maxillofac Surg. 1992; 21: 140-144.

5. De Sutter E, Dhooghe P, Baert C. Marlex mesh in the reconstruction of blow-out fractures of the orbit. Bull Soc Belge Ophtalmol. 1988; 228: 47.

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Use of Porous Polyethylene With Embedded Titanium in Orbital Reconstruction: A Review of 106 Patients

Daniel C. Garibaldi, M.D., Nicholas T. Iliff, M.D.,
Michael P. Grant, M.D., Ph.D., and Shannath L. Merbs, M.D., Ph.D.

The Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, Maryland, U.S.A.

Purpose: To evaluate our initial experience with a porous polyethylene implant with embedded titanium in orbital reconstruction.

Methods: A retrospective review of the charts was performed for patients receiving at least 1 orbital porous polyethylene implant with embedded titanium from October 2004 through April 2006. Patient demographics, implant type and size, method of fixation, postoperative complications, and length of follow-up were recorded.

Results: One-hundred six patients received at least one embedded titanium implant (80 men, 26 women). Age ranged from 3 years to 85 years (mean, 31 years). Indications included orbital fracture repair (102 patients), correction of enophthalmos (3 patients), and reconstruction after tumor resection (1 patient). The average floor implant used was 22.3 mm wide by 27.9 mm long. The average medial wall implant was 13.6 mm tall by 22 mm long. Implants were fixated with 1 or 2 microscrews in 75 patients (70.8%) and placed without fixation in 31 patients (29.2%). Four postoperative complications were noted: a retrobulbar hemorrhage on postoperative day 3 that resolved without sequelae, a vertical overcorrection requiring removal of the implant, a transient oculomotor disturbance, and a screw placed in proximity to the infraorbital nerve canal resulting in hypesthesia and chronic pain that required removal of the screw. In the 3 complications potentially related to the implant, the embedded titanium allowed postoperative implant visualization and guided subsequent management. No implant extrusions or postoperative infections were noted.

Conclusions: Porous polyethylene implants with embedded titanium provide a new alternative to alloplastic implant materials for orbital reconstruction with a profile that combines several advantages of porous polyethylene and titanium implants.

Successful orbital reconstruction following traumatic fracture or orbital surgery depends on thoughtful preoperative planning, meticulous operative dissection, and proper selection of implant type, size, and contour. Numerous materials have been used in internal orbital reconstruction, including autologous grafts (such as bone or cartilage), alloplastic materials (such as silicone, nylon sheets, polytetrafluoroethylene, hydroxyapatite, gelatin film, and porous polyethylene), and metal sheets or mesh (such as titanium or vitallium alloys).[1] Each type of implant possesses unique performance characteristics that determine its utility in particular reconstructive settings, such as ease of insertion, degree of structural support, requirement for fixation, and ability to retain a shape once contoured.

Two of the most common implant materials currently used are titanium alloy mesh and porous polyethylene (PP). Titanium mesh has been used with good success in orbital reconstructions.[1–7] In vivo, titanium is biocompatible and demonstrates integration in adjacent bone, limiting postoperative migration of implants.[2] Microscrews also can be used to fixate the mesh to bone.[8,9] Titanium mesh has significant tensile strength and, because of its malleability and memory, it can be contoured to fit virtually any internal orbital defect. In addition, titanium is easily visualized on postoperative CT. However, titanium does promote a cellular-based inflammatory response leading to development of a double-layered connective tissue envelope,[10] and can be difficult to insert through small incisions because of sharp or irregular edges.

Porous polyethylene is a high-density polyethylene with an interconnecting array of micropores that allow for fibrovascular ingrowth in the implant.[11] This structure maintains the rigidity of polyethylene while allowing self-fixation in surrounding tissues.[12,13] Multiple

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studies have suggested that PP implants offer advantages over other graft materials in craniofacial and orbital reconstructions.[14–16] However, PP sheets are less malleable and have less memory than titanium mesh and are not readily visualized on postoperative imaging studies.

Recently, an implant has been developed that embeds a thin titanium mesh between two sheets of high-density polyethylene. The high-density polyethylene can be porous, allowing for fibrovascular ingrowth, or nonporous, acting as a barrier to tissue ingrowth. These implants were designed to combine the advantages of both titanium and PP, while minimizing the disadvantages of each. We present our initial experience with these implants in 106 patients.

METHODS

Internal Review Board exemption was obtained for the study. Patients who received embedded titanium implants were identified by retrospectively searching operative billing records for 3 surgeons (SLM, NTI, MPG) from October 2004 through April 2006 using Current Procedural Terminology codes for blowout fracture repair with implant (21390); fracture of orbit, except blowout, with implant (21407); and placement of orbital implant outside muscle cone (67550). This search was designed to capture all patients that could potentially have received embedded titanium implants during the study period. Operative reports were reviewed, and patients who did not receive embedded titanium implants during their surgical repair were excluded. Preoperative and postoperative records were reviewed to discern patient demographics, implant type and size, method of intraoperative fixation, and postoperative complications associated with the implant.

RESULTS

During the 19-month study period, 106 patients received at least 1 embedded titanium implant (80 men, 26 women). Patient age ranged from 3 years to 85 years (mean, 31 years). Indications included orbital fracture repair (102 patients), correction of enophthalmos (3 patients), and orbital reconstruction after tumor resection (1 patient). Fifty-six patients had isolated floor fractures, 2 had isolated medial wall fractures, and 1 had an isolated roof fracture. Of the 43 patients with floor fractures in combination with other injuries, 27 had medial wall fractures, 7 had zygomatic fractures, 4 had orbital rim fractures, 4 had nasal fractures, and 1 had a roof fracture. Of the 27 patients with combined medial wall and floor fractures, 9 medial wall fractures were left unrepaired, 4 were repaired using embedded titanium implants (including 1 implant that spanned both the medial wall and floor fracture), 10 with PP single-channel implants, 3 with PP flex block implants, and 1 with a PP implant.

A total of 100 patients received 1.0-mm-thick Medpor Titan Barrier (MTB) (Porex Surgical, Fairburn, GA, U.S.A.) plates and 6 received Medpor Titan Double Barrier (Porex Surgical) plates. These patients received a total of 110 embedded titanium implants: 101 floor implants, 5 medial wall implants, 1 implant that spanned both the medial wall and floor fracture, 2 roof implants, and a lateral wall implant. Dimensions were available for 92 of the 101 floor implants, and the average size used was 22.3 mm wide by 27.9 mm long, with the implant tapered posteriorly to approximately 10 mm wide. The average medial wall implant was 13.6 mm tall by 22.0 mm long. Implants were fixated with 1 or 2 microscrews in 75 patients (70.8%) and were placed without fixation in 31 patients (29.2%).

Follow-up was available for 102 patients (96.2%) with a range of 1 week to 17.5 months (mean, 3.5 months). Four early postoperative complications potentially related to the implant were noted (3.9%). These included a retrobulbar hemorrhage on postoperative day 3 that resolved without sequelae, a vertical overcorrection requiring removal of the implant, a transient oculomotor disturbance in a patient undergoing delayed enophthalmos correction thought to be related to intraoperative traction, and infraorbital nerve hypesthesia related to a fixation screw adjacent to the infraorbital nerve. The hypesthesia resolved after screw removal. In the 3 other cases outlined below, the presence of titanium in the implant allowed postoperative visualization of the implant and guided the subsequent management. No implant extrusions or postoperative infections were noted.

Case 1. A 27-year-old man presented with facial deformity following a motor vehicle collision 2 years prior to presentation. He had undergone acute repair elsewhere at the time of his injury. Examination disclosed visual acuity of 20/20 OU with an unremarkable slit lamp examination. Extraocular motility was minimally restricted in upgaze and downgaze with subjective diplopia at extremes of gaze. External examination disclosed severe left hypoglobus and enophthalmos. CT revealed a depressed and externally rotated left zygoma fracture with miniplate fixation and an undercorrected left orbital floor fracture with what appeared to be partially resorbed bone graft.

Surgery was performed and the patient's malar deformity was addressed using a PP orbital rim implant. The orbital floor fracture was repaired through a transconjunctival incision with a 24 mm wide × 29 mm long MTB implant that was tapered posteriorly. The implant was fixated laterally using a 1.3-mm self-drilling titanium screw. The patient was admitted for overnight observation and was discharged the next morning without complication. On the day of discharge, postoperative CT disclosed an anatomic reconstruction of the orbital floor (Fig. 1A). On postoperative day 3, the patient was evaluated for periorbital swelling and mild bleeding from his transconjunctival incision, which began after he blew his nose the previous evening. Examination disclosed visual acuity of 20/30 with normal pupils and slight generalized restriction of extraocular motility, unchanged from his initial postoperative examination. External examination disclosed 4 mm of left proptosis with inferior hemorrhagic chemosis (Fig. 1B). Intraocular pressure was 21 mm Hg OS. Dilated examination disclosed a normally perfused optic nerve without disc swelling. Because the postoperative CT disclosed optimal implant positioning, we elected to follow the patient. His swelling and chemosis resolved without sequelae with correction of his preoperative enophthalmos and hypoglobus (Fig. 1C).

Case 2. A 35-year-old woman presented with double vision after having been struck by a softball 7 months prior to

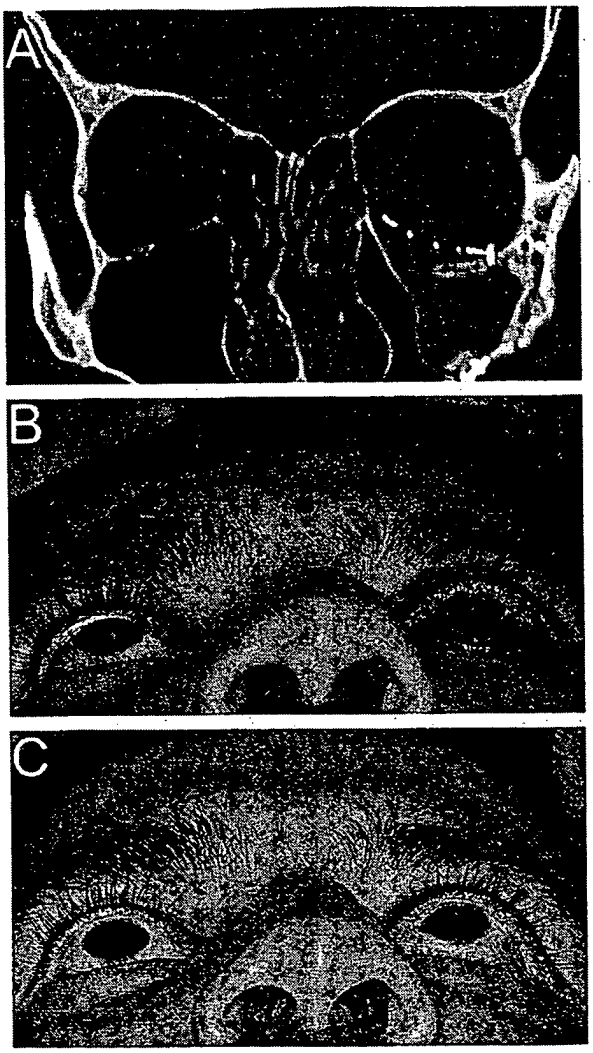

FIG. 1. Retrobulbar hemorrhage after repair of orbital floor fracture. A, Postoperative CT confirms stable placement of implant on bony ledges of floor fracture. B, Left hemorrhagic conjunctival chemosis and proptosis in setting of presumed retrobulbar hemorrhage. C, Near resolution of chemosis and proptosis 1 week later.

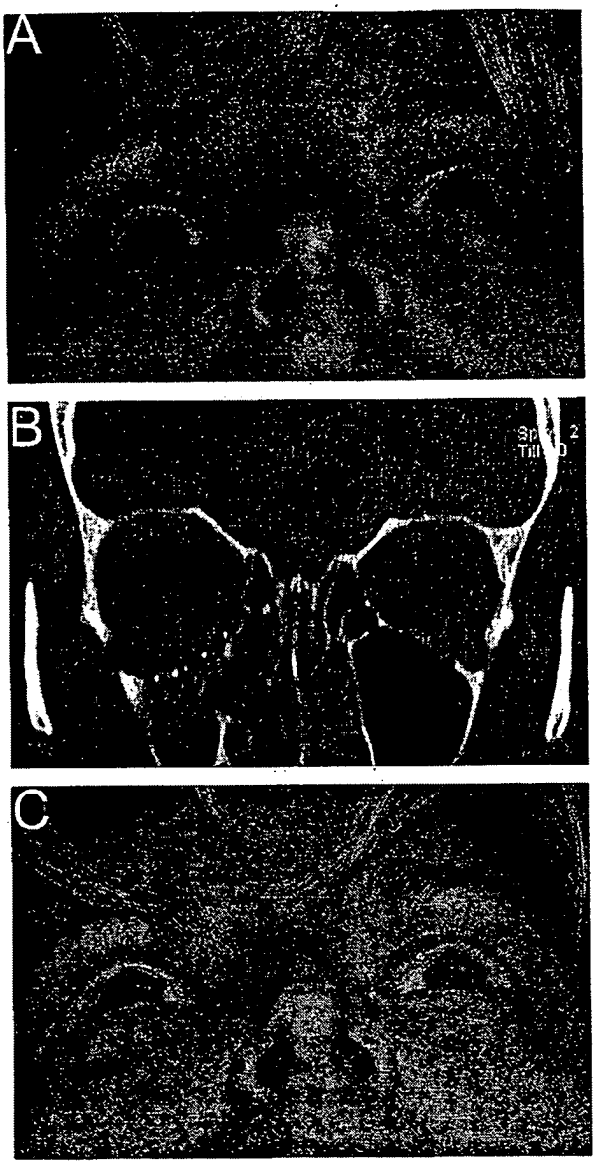

FIG. 2. Oculomotor disturbance after orbital floor fracture repair. A, Preoperative photo demonstrates severe right enophthalmos and hypoglobus in setting of unrepaired large orbital floor and medial wall fractures. B, Postoperative CT demonstrates excellent placement of floor implant. C, Postoperative photo demonstrates the resolution of the preoperative volume loss and a dilated right pupil.

presentation. No acute intervention had been recommended by her primary care physician. Examination disclosed visual acuity of 20/20 OU with a normal pupillary exam. External examination revealed right enophthalmos and hypoglobus (Fig. 2A). Extraocular motility was essentially full, except for minimal restriction and pain on far upgaze on the right. Slit lamp and dilated fundus exams were unremarkable. CT disclosed large medial wall and floor fractures on the right with herniation of orbital contents in the adjacent sinuses.

During repair of the orbital floor via a transconjunctival incision, the orbital contents were reposited from the maxillary sinus and a 25 mm wide × 29 mm long MTB plate tapered posteriorly was fashioned to cover the bony defect. During placement of this plate, dilation of the patient's pupil was noted. Fundus examination disclosed a well-perfused optic nerve and retina. The plate was fixated using a self-drilling 1.3-mm screw, and repair of the medial wall fracture was deferred.

In the postoperative recovery area, the pupil remained dilated; however, the patient's vision on the right was 20/25 and an afferent pupillary defect was absent by reverse testing. The patient was admitted for observation and CT confirmed the optimal placement of the MTB implant on the stable bony ledges surrounding the fracture with no compromise of the optic nerve (Fig. 2B). On postoperative day 1, the patient

continued to have a dilated pupil and was noted to have a generalized limitation of motility on the right (Fig. 2C). Given the appropriate location of the implant without evidence of posterior migration to indicate an orbital apex or superior orbital fissure syndrome, we elected to observe the patient. We attributed her motility deficiencies and dilated pupil to multiple cranial neuropathies secondary to intraoperative traction needed to gain adequate exposure for a late enophthalmos repair. These completely resolved after a few months.

Case 3. A 58-year-old woman presented acutely with a large right orbital floor fracture and nondisplaced maxillary fracture after a fall. Given early enophthalmos and subjective diplopia in upgaze and downgaze, she underwent uncomplicated repair of the floor fracture using a 25 mm wide × 29 mm long MTB plate that was left unfixated. Immediately postoperatively, she did well. However, at a 7-month postoperative visit, the patient was noted to have 1.5 mm of proptosis on the affected side with 1 mm of hyperglobus (Fig. 3A). CT disclosed that the anterior aspect of the implant was well positioned, but the posterior aspect of the implant rested several millimeters superior to the posterior ledge of the fracture (Fig. 3B, C), despite the fact that the implant had not been fixated with an anterior screw that can occasionally cause the posterior aspect of implants to pivot superiorly. The implant was explanted via a transconjunctival incision without difficulty. At 1-month follow-up the proptosis had resolved, leaving trace hyperglobus on the right side. Shortly thereafter, the patient was lost to follow-up because of severe pulmonary dysfunction secondary to advanced lung cancer.

DISCUSSION

The choice of the "ideal" implant to use in orbital reconstruction is based primarily on the size and location of the orbital defect and the remaining structural support available to support the implant. Many different implant materials have been used, each with its own advantages and disadvantages. While autologous bone provides the highest degree of biocompatibility, it lacks malleability and thus is difficult to shape, is subject to reabsorption, and has a risk of donor site morbidity. Other implants, such as silastic sheets, lack sufficient tensile strength to provide support for large fractures.

PP with embedded titanium possesses the advantages of both PP and titanium, while minimizing the disadvantages of each. Like titanium, it provides excellent structural support for large fractures, is malleable, and maintains it contour once shaped. Like PP, it allows rapid host integration via fibrovascular ingrowth and is resistant to infection. Host integration allows implant placement without fixation, which can be difficult in some cases of limited anterior support. Self-fixation also can decrease the risk of iatrogenic trauma to the infraorbital nerve by screw placement, given that previous studies have reported postoperative infraorbital anesthesia with fixation of orbital implants as a significant complication following orbital floor reconstruction.[2,17,18] A large cohort and long-term follow-up would be necessary to ascertain an outcome difference between fixated and nonfixated implants, as related to infraorbital anesthesia, implant migration, or extrusion. In our series, 29.2% were fixated with at least 1 screw.

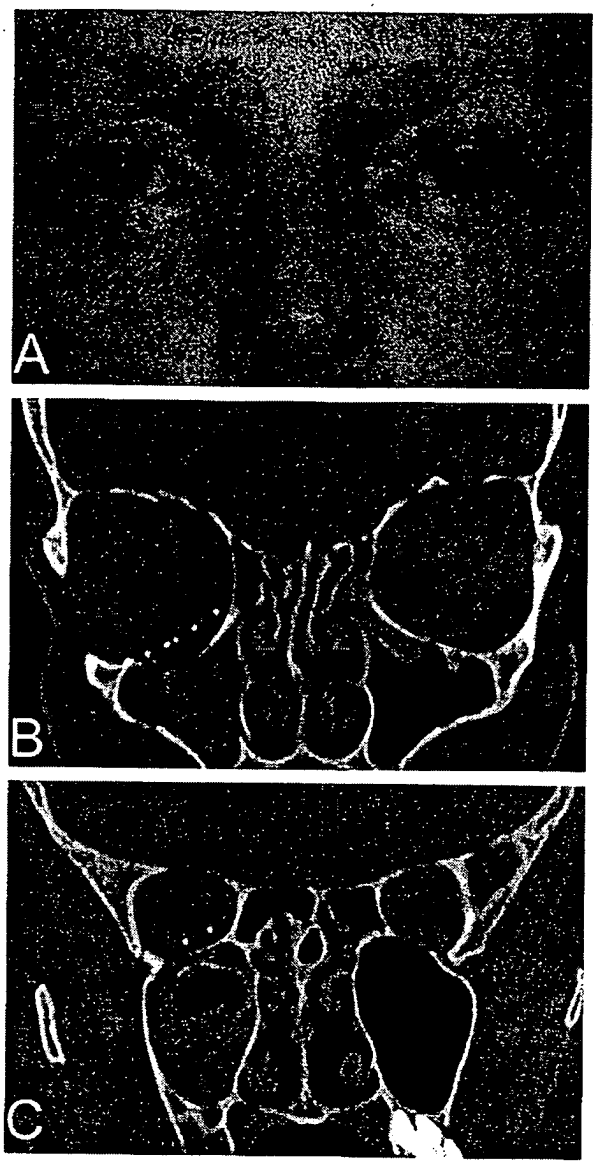

FIG. 3. Overcorrection following orbital floor fracture repair. A, Clinical photo demonstrates right hyperglobus and proptosis following repair of orbital floor fracture. B, CT shows that the anterior aspect of the implant is well-positioned. C, CT shows the posterior aspect of the implants resting several millimeters above the posterior ledge of the fracture.

With their barrier coating, MTB and Medpor Titan Double Barrier implants are easier to insert than either titanium or PP. These implants are easily inserted through a transconjunctival incision without lateral canthotomy with minimal risk of iatrogenic trauma to the

eyelid or postoperative eyelid malposition. Intraoperatively, the barrier surface helps to serve as a smooth nonadherent retractor during implant placement, ensuring that orbital tissues are free of the sinus while the placing the implant on the posterior ledge of the fracture. The barrier surface also prevents adherence of the orbital tissues to the implant postoperatively. This is particularly important in the setting of orbital trauma, where scar tissue can affix to alloplastic implants if the periorbita has been violated, resulting in postoperative restrictive strabismus. In rare cases where the implant must be removed (as in Case 3), the porous underside of the implant is easily dissected free from its attachments to mucosa and remnants of orbital bone, while the barrier surface of the implant prevents integration of orbital tissues.

Medpor Titan Double Barrier implants have barrier coating on both sides and have a slightly thinner profile than the MTB implants. The thinner profile can serve as an advantage in smaller fractures that do not require structural support, such as a trapdoor fracture. A disadvantage of this implant is that in general fixation is required, given the lack of tissue ingrowth. This can lead to complications associated with fixation, as described above.

Postoperative complications have been reported with virtually every type of orbital implant. These include implant-related infections,[19–23] migration of the implant or extrusion, [21,24–26] fistulization,[21,27] restrictive strabismus,[21,28] globe displacement via implant malposition or size,[21] and late hemorrhage in the capsule surrounding the implant.[29] Our complication rate (3.9%) is similar to that observed for other large cohorts undergoing orbital reconstruction using alloplastic implants, though our follow-up is shorter. Nam et al.[17] observed a complication rate of 5.6% and 9.4% in 214 patients receiving PP and 191 receiving hydroxyapatite implants, respectively, for the repair of orbital fractures. Eleven patients required reoperation (2.7%). Ng et al.[18] reported 4 postoperative complications in 30 patients undergoing blowout fracture repair with PP (13.3%), including recurrent infection leading to implant removal, infraorbital anesthesia, and a palpable fixation screw. Gear et al.[2] reported 1 major complication (a postoperative abscess) in 55 patients receiving titanium mesh for orbital fracture repair (44 patients with follow-up sufficient for inclusion in the authors' analysis). Of our 4 complications, only the vertical overcorrection seen in case 3 can be related specifically to the characteristics of the chosen implant, because the rigid implant maintained a superiorly displaced posterior aspect that displaced the globe vertically. Longer follow-up of our patients is needed to evaluate the risk of late complications of embedded titanium implants.

We cannot understate the value of being able to accurately evaluate the position of an orbital implant on postoperative imaging studies. While the utility, safety, and cost effectiveness of postoperative orbital and maxillofacial imaging has been debated, studies have shown that orbital implants perceived as optimally placed often are malpositioned and can contribute to postoperative undercorrection or complication.[30] Since we began using embedded titanium implants, we have routinely performed postoperative CT to scrutinize our implant placement. In addition to the structural advantages to the implant outlined above, we feel that the radio-opaque nature of the embedded titanium implants offers 2 other advantages over PP implants without titanium.

First, the use of thin coronal and sagittal CT images allows the surgeon to visualize the relation of the implant to the bony ledges surrounding the fracture and compare the postoperative location of the implant to intraoperative observations. This can prove especially valuable for surgeons in training and for surgeons using embedded titanium implants after becoming accustomed to other materials. One disadvantage that embedded titanium shares with titanium mesh is that the rigid nature of the implant allows it to override the posterior ledge superiorly during placement. In fact, we noted that in several early cases, the posterior aspects of our embedded titanium floor implants rested superior to the posterior fracture ledge (as in case 3 above) on postoperative CT. Based on this observation, we now impart a subtle downward bend to the most posterior aspect of the implant, to allow it to more easily rest on the posterior ledge of the fracture (Fig. 4).

Second, knowing the precise location of the orbital implant allows us to confidently evaluate postoperative clinical findings and manage postoperative complications. In cases of persistent enophthalmos, presumed overcorrection, or persistent strabismus, we are able to radiographically visualize implant placement to evaluate whether plate malposition is contributing to the postop-

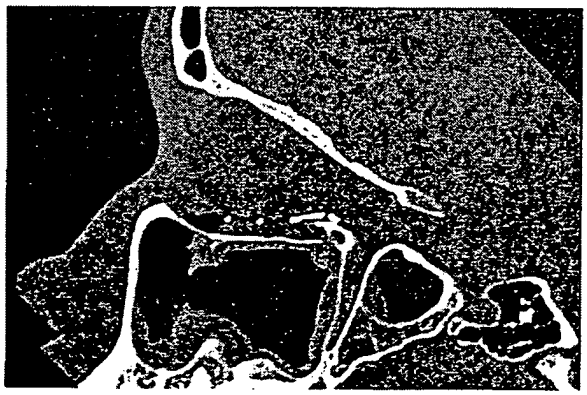

FIG. 4. Posterior contour of the orbital floor implants. CT following repair of an orbital floor fracture demonstrates the subtle bend the authors impart to their floor implants to follow the contour of the posterior ledge.

erative clinical findings. In each of our 4 complications, the postoperative scan was essential in developing a management plan, and in the first 3 cases, the radiopaque nature of the implant was crucial. Had our implants been PP without embedded titanium, determining the proper management for these patients might have proved more challenging.

In summary, we feel that PP implants embedded with titanium are safe and effective for orbital reconstructive surgery and possess performance characteristics that combine favorable attributes of PP and titanium implants. Given that this was a retrospective review, with all the inherent limitations of a retrospective work, further prospective studies could be of benefit to compare PP implants embedded with titanium directly to other available alloplastic materials. Studies allowing longer follow-up are needed to assess the risk of late complications.

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